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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,204	01/18/2005	Frank Brady	PH0249	3678
36335 7590 02/06/2007 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			EXAMINER NAGUBANDI, LALITHA	
			ART UNIT	PAPER NUMBER
			1621	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/522,204	Applicant(s) BRADY ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on elc. 12/27/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/2005</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of the Claims

Claims 1-8 are pending. Claims 1-6 are considered in this office action.

Election/Restrictions

Applicants' election without traverse of Group I claims 1-6, and Example 2, (N- (2-chloro-5- (methylthio) phenyl)-N- (3-methylthio) phenyl)-N'- [¹⁸F]-fluoromethylguanidine, as the species for claims 1-4 and 6, in the reply to our earlier office action dated November 24th 2006 is acknowledged. Claims 7 and 8 are withdrawn from further consideration as they are drawn to non-elected group. The election requirement dated November 24th 2006 is made **FINAL**.

Priority

This application is a 371 of PCT/GB03/03078 dated July 16th, 2003, which claims priority to United Kingdom Patent application no. 0216621.3 dated July 17th, 2002.8

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is

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requested in correcting any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

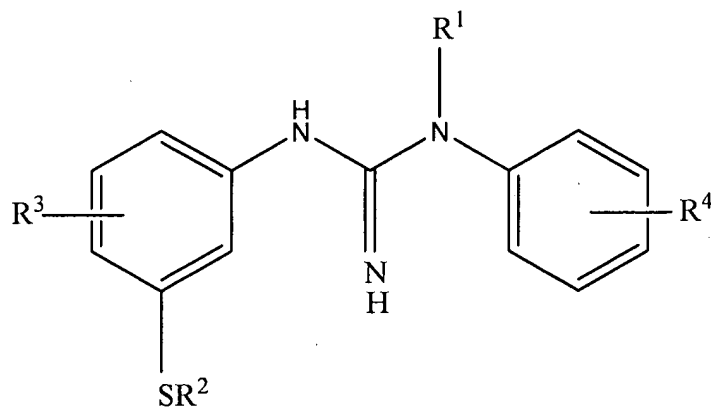
Claims 1- 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Waterhouse et al (Journal of Labelled Compounds and Radiopharmaceuticals 2002; 45: 955-964

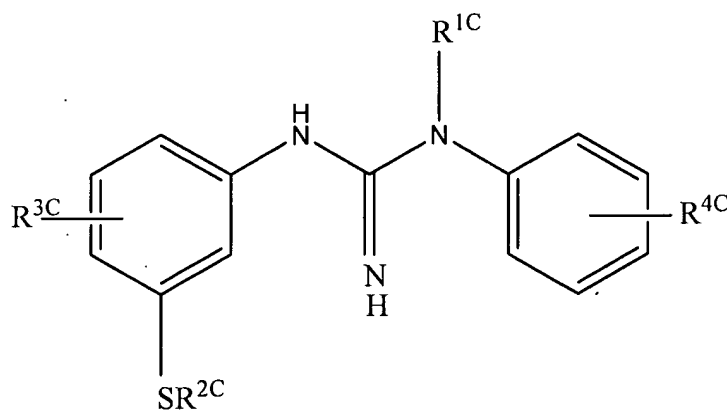
And Wieland et al (J. Med. Chem. 1984, 27, 149-155) in view of Shields et al (J. Nucl. Med. 1992; 33: 581-584).

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Applicants claim a compound of **Formula (I)**:



Formula (Ic)



Wherein, R^1 , R^2 , R^3 , and R^4 are as defined. The compounds further contain R^1 as ^{11}C -alkyl or $-\text{CH}_2^{18}\text{F}$, to $-\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2^{18}\text{F}$ and R^{3c} is radioiodine (see formula Ic). The instant compounds are claimed to be useful in diagnostic studies like Positron Emission Tomography (PET).

Determination of Scope and content of the Prior Art (MPEP § 2141.01)

Waterhouse et al teach synthesis of guanidine derivatives (see Table 1, page 961, Journal of Labelled Compounds and Radiopharmaceuticals 2002; 45: 955-964) Further, Waterhouse teaches the Radio synthesis of PET tracer [^{11}C] GMOM (see page 962 Scheme 2).

Wieland et al teach (J. Med. Chem. 1984, 27, 149-155) radiolabelled aralkylguanidines particularly the radiolabelled Iodo guanidine derivatives (see page 150, Table 1). Further, Shields et al teaches the metabolism of radiolabelled compounds and their use in imaging studies (see the whole document).

Ascertainment of the difference between the Prior Art and Claims (MPEP § 2141.02)

The difference between the instant compounds and Waterhouse et al is that some of the instant compounds requires tracer element like ^{11}C at the N'-Me position of the guanidine moiety and N-Me, Carbon is substituted with ^{18}F tracer element. Though Wieland teaches radiolabelled guanidine derivatives the compounds are not identical to the instant invention.

Finding of prima facie obviousness – rational and motivation (MPEP § 142-2143)

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant compounds by modifying the substitutions around the core structure, since the diphenyl substituted guanidine core is already known in the prior art. Introduction of a tracer element like ^{11}C or ^{18}F at the N-Me position of the guanidine or at other substituents would have been obvious to one skilled in the radiosynthetic field. The examiner contends that the

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combination of references is proper and an ordinary artisan would have had a reasonable expectation of success at the time of the instant invention to arrive at the instant imaging compounds and hence it is prima facie.

Conclusion

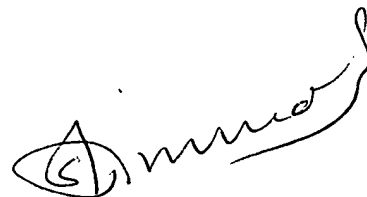
No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

February 3rd, 2007.



Shailendra Kumar.
Primary Patent Examiner
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